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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,212	06/07/2002	Atsushi Miyamoto	Q68293	4780

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
SUITE 800  
WASHINGTON, DC 20037

EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/048,212	Applicant(s) MIYAMOTO ET AL.	
	Examiner Lisa V. Cook	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 4-6, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 6, 9, and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Amendment Entry*

1. Applicants response to the Office Action mailed March 30, 2005 is acknowledged (paper filed 8/30/05). In the amendment filed therein, the specification along with claim 1 and claim 6 were modified. Claims 2, 3, 7, and 8 were canceled without prejudice or disclaimer. Currently, claims 1, 4-6, and 9-10 are pending and under consideration.
2. Objections and/or rejection of record not reiterated herein have been withdrawn.

## NEW GROUNDS OF REJECTION

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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I. Claims 1, 4, 6, and 9 are rejected under 35 U.S.C.103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Shinoda et al. (Nippon Ishinkin Gakkai Zasshi, 1991, 32 Suppl.2 Proc. Annu. Meet. Jpn. Soc. Med. Mycol. 34<sup>th</sup> 1990, pages 83-93, Abstract Only).

Hunter et al. teach agglutination procedures to measure antibody-antigen binding. In one embodiment, pepsin treated antibodies are coupled to BSA (protease treated BSA) and use to measure antigen interaction via agglutination. See pepsin of F(ab)<sub>2</sub> fragments and 7S on page 356; page 363. Bovine serum albumin (BSA) is proven useful in being coupled to reagents while the reagent binding ability in agglutination procedures is maintained. See page 361 number 2 and table IV.

Hunter et al. differ from the instant invention in not specifically teaching the utility of latex particles carrying an antibody or antigen specifically reactive with the analyte of interest.

However, Shinoda et al. teach this limitation. Specifically, Shinoda et al. disclose agglutination tests to measure cryptococcal antigens. The test utilizes a protease treated serum or cerebrospinal fluid sample and a sensitized latex suspension (particles coated with anti-Cryptococcal). The antigen was detectable in soluble immune complexes. The latex assay was sensitive and useful in patient sample evaluations (meningitis, pulmonary cryptococcosis, and cutaneous cryptococcosis). The protease pretreatment of the serum was useful in reducing false positive and false negative results. See abstract.

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It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to use a latex assay as taught by Shinoda et al. in the BSA protease pretreatment method of Hunter et al. because Shinoda et al. taught that the latex assay was sensitive and useful in patient sample evaluations (meningitis, pulmonary cryptococcosis, and cutaneous cryptococcosis). Further, the protease pretreatment was useful in reducing false positive and false negative results in the latex assay. See abstract.

II. Claims 5 and 10 are rejected under 35 U.S.C.103(a) as being unpatentable over Hunter et al. (Int. Arch. Allergy, 36 354-375, 1969) in view of Shinoda et al. (Nippon Ishinkin Gakkai Zasshi, 1991, 32 Suppl.2 Proc. Annu. Meet. Jpn. Soc. Med. Mycol. 34<sup>th</sup> 1990, pages 83-93, Abstract Only) and further in view of Nakase et al. (JP 48019719 Abstract Only).

Please see Hunter et al. in view of Shinoda et al. as set forth above. Hunter et al. in view of Shinoda et al. disclose the reagent combination involving protease treatment in combination with BSA and antigen/antibody coated latex particles. However, Hunter et al. in view of Shinoda et al. do not teach the use of these reagents for anti-streptolysin O antibodies.

Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

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Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the protease treatment in combination with BSA and antigen/antibody coated latex particles detection reagents as taught by Hunter et al. in view of Shinoda et al. and utilize them in turbidity measurements for anti-streptolysin O antibodies/antigen assays because Nakase et al. disclose that the addition of BSA (bovine serum albumin) to streptolysin O stabilizes streptolysin O and allow streptolysin O to maintain its activity. See abstract.

### ***Response to Arguments***

Applicants contend that the reference of Masson et al. did not anticipate the instant invention because BSA was carried on the latex particle and not protease treated as set forth in the claims. This argument was carefully considered and found persuasive. Accordingly the reference to Masson et al. has been replaced with Hunter et al. in view of Shinoda et al.

4. For reasons aforementioned, no claims are allowed.

### ***Remarks***

5. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Masson et al. (EPO 0 061 857 A1) disclose pepsin digestion to eliminate protein interferences. See page 8 lines 25 through 30.

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6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



*Lisa V. Cook*  
Remsen 3C-59  
(571) 272-0816  
11/3/05



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
11/09/05